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NHS Forth Valley

ADTC Newsletter
New Drugs & Therapeutic Advances

Outlined below in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix I).

Please remember that the ADTC advises prescribers **not** to prescribe any drug that has been rejected by Scottish Medicines Consortium (SMC) or has not yet been considered by SMC.

Where a medicine is not recommended for use by the Scottish Medicines Consortium (SMC) for use in NHS Scotland, including those medicines not recommended due to non-submission, this will be noted by the Area Drug and Therapeutics Committee New Drug Sub Group and the medicine will not be added to the NHS Forth Valley Formulary.

Where a medicine that has not been accepted by the SMC or NHS Health Improvement Scotland (HIS) following their appraisal on clinical and cost-effectiveness, there is a Individual Patient Treatment Request (IPTR) process which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to pursue approval for prescribing, on a "case by case" basis for individual patients

A copy of this policy can be found at the Pharmacy page on the Intranet on the following link:
http://intranet.fv.scot.nhs.uk/web/FILES/Pharmacyfiles/NHSFVIPTRpolicywithappendicesv1_3final.pdf

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the Quality Improvement Website on the link below.

http://www.qifv.scot.nhs.uk/

New West of Scotland Guideline for Prescribing of Opioids in Chronic Non-Malignant Pain

This new guideline provides a practical framework to enable potent opioids to be prescribed in the most effective, safe and consistent way for chronic non-malignant pain.

The guideline includes:

- advice on determining the suitability for, and the conduct of, an opioid trial
- advice on choice of opioid (**Morphine** is clearly positioned as the first-choice strong opioid)
- recommendations on long-term monitoring of the patient
- a range of practical, easy to use tools including an ongoing assessment tool and an opioid risk tool

The guideline also includes opioid equivalences and prescribing algorithm making it easy to use.

New advice contained in the guideline: any patient requiring a dose higher than 60mg Morphine Sulphate SR Tablets twice daily or equivalent should be referred to a pain specialist.

The guideline is available from the QI Website http://www.qifv.scot.nhs.uk/ (under Pain Management).

Drugs Not Approved By the Scottish Medicines Consortium

Prescribing of SMC non-recommended drugs is monitored nationally by the Information Services Directorate (ISD) of the NHS National Services Scotland and reported to the Forth Valley Primary Care Pharmacy Services. As part of our locally agreed process, practices will be routinely notified on a quarterly basis of any items which are not recommended for use, and advised to review therapy.

The Acute Services will similarly be monitoring the use of SMC non-recommended drugs and will feedback usage to their Executives via the Finance Report.

SMC Independent Review Panel

Where there are no significant new data or analyses, the sponsor company may ask that SMC convenes an Independent Review Panel (IRP) to look again at the existing data and analyses. An IRP may only be requested after a first SMC assessment has been completed, but can then be requested at any time when the drug is not in an SMC assessment process.

The IRP will be appointed by the SMC on the advice from the Chairman and Secretariat, and shall comprise 7 members:

- 3 members (where possible) appointed from the SMC/NDC (people who, by reason of absence, have not previously been involved in the particular submission, including former members of SMC or NDC), one of whom shall be appointed to chair the panel.
- 4 members (or more if required) appointed from Scottish Area Drug and Therapeutics Committees (or their successors/equivalents) and/or other respected experts in the relevant scientific field, who need not necessarily be working in Scotland.

The IRP will review the original submission(s) considered by the pharmacy and health economic assessment teams, the output from these review teams and the views of the NDC and SMC. Should support and advice be required then this shall be provided by the usual Assessment Teams, but will be provided by persons not involved in the original review(s)/ assessment(s).

The timeline from notification to request an IRP and publication of the final SMC advice is expected to be at least 6 months, due to the requirement to convene the panel and chair.

The IRP will report back to the SMC who shall remain the final arbiter in all cases.

The SMC has advised that the following drugs are **not** recommended for use in NHS Scotland.

Generic Name & Formulation	Brand Name	Indication
Aflibercept 25mg/mL concentrate for solution for infusion	*Zaltrap®*	In combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.
Canakinumab 150mg powder for solution for injection	*Ilaris®*	Treatment of Cryopyrin Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5kg or above including: • Muckle-Wells Syndrome (MWS) • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, cutaneous, Articular Syndrome (CINCA) Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.
Canakinumab 150mg powder for solution for injection	*Ilaris®*	Symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

Generic Name & Formulation	Brand Name	Indication
Chloroprocaine hydrochloride, 10mg/ml, solution for injection	*Ampres*®	Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes.
Everolimus 10mg tablet	*Votubia*®	Treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.
Eculizumab 300mg concentrate for solution for infusion	*Soliris*®	In children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of soliris in the treatment of patients with PNH is limited to patients with history of transfusions.
Everolimus, 5mg and 10mg tablets	*Afinitor*®	Treatment of hormone receptor-positive, human epidermal growth factor type 2 (HER2)/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.
Fluocinolone acetonide 190 micrograms intravitreal implant	*Iluvien*®	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.
Ivacaftor 150mg film-coated tablets **Resubmission**	*Kalydeco*®	Treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the cystic fibrosis transmembrane conducatance regulator (CFTR) gene.
Nomegestrol acetate/estradiol film-coated tablets	*Zoely*®	Oral contraception.
Ocriplasmin, 0.5mg/0.2mL, concentrate for solution for injection	*Jetrea*®	In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns.

NICE guidance

NICE Single technology Appraisal (STA): SMC is the source of advice for Scotland on new drug therapies and the NICE STA process therefore has **no status in Scotland**. If a NICE STA endorses a drug that was not recommended by the SMC, it is open to the manufacturers to resubmit the drug to SMC with new evidence.

NICE Multiple Technology Appraisal (MTA): NHS Quality Improvement Scotland (NHS QIS) reviews MTAs and decides whether the recommendations should apply in Scotland where Health Improvement Scotland (HIS) decides that an MTA should apply in Scotland, the NICE guidance supersedes SMC advice. Unlike the SMC process, MTAs examine a disease area or a class of drugs and usually contain new evidence gathered after the launch of drugs or new economic modelling.

This information is reviewed by the New Drugs group on a routine basis.

HIS Comments on NICE Single Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE (Single) Technology Appraisal Guidance No 280 – Rheumatoid arthritis (2nd line) – abatacept (rapid review of TA234)	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA280**	**Accepted for restricted use** **Indication under review:** in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor	8/4/13	**Yes**
NICE (Single) Technology Appraisal Guidance No 281 – Canakinumab for gout – terminated appraisal	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA281**	**Not recommended** **Indication under review:** symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate	10/5/13	**No**
NICE (Single) Technology Appraisal Guidance No 282 – Idiopathic pulmonary fibrosis – pirfenidone	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA282**	**Accepted for restricted use** **Indication under review:** in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF)	12/8/13	**Yes**
NICE (Single) Technology Appraisal Guidance No 283 – Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA283**	**Accepted for use (Resubmission)** **Indication under review:** for the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. The resubmission relates to branch RVO only	13/5/13	**Yes**
NICE (Single) Technology Appraisal Guidance No 284 – Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA284**	**Not recommended** **Indication under review:** bevacizumab in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary pertitoneal cancer	8/10/12	**No**

HIS Comments on NICE Single Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE (Single) Technology Appraisal Guidance No 285 – Bevacizumab in combination with gencitabine and carboplatin for treating the first recurrence of platinum-sensitive advanced ovarian cancer	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA285**	**Not recommended** **Indication under review:** bevacizumab, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelian ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents	11/3/13	**No**
NICE (Single) Technology Appraisal Guidance No 286 – Loxapine inhalation for treating acute agitation and disturbed behaviours associated with schizophrenia and bipolar disorder (terminated appraisal)	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA286**	**Not been through SMC**		**No**
NICE (Single) Technology Appraisal Guidance No 287 – Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA287**	**Accepted for use** For the treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults	11/3/13	**Yes**
NICE (Single) Technology Appraisal Guidance No 288 – Dapagliflozin in combination therapy for treating type 2 diabetes	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA288**	**Accepted for restricted use** For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: Add-on therapy; In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction**: Dapagliflozin is restricted to use as dual therapy in combination with metformin, when metformin alone and diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate	14/1/13	**Yes**
NICE (Single) Technology Appraisal No 289 – Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA289**	**Not recommended** **Indication under review:** Treatment of disease-related slenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis	8/4/13	**No**
NICE (Single) Technology Appraisal No 290 – Mirabegron for treating symptoms of overactive bladder	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA290**	**Accepted for use** **Indication under review:** For symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome	13/5/13	**Yes**
NICE (Single) Technology Appraisal No 291 – Pegloticase for treating severe debilitating chronic tophaceous gout	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA291**	**Not been through SMC**		**No**

HIS Comments on NICE Single Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE (Single) Technology Appraisal No 292 – Aripiprazole for treating moderate to severe manic episodes in adolescents with bipolar I disorder	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA292**	**Accepted for restricted use** Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. **SMC restriction**: restricted to initiation and management under the supervision of a child/adolescent psychiatrist.	8/6/09	**Yes – on formulary under section: 4.2 – Drugs in psychoses and related disorders**
NICE (Single) Technology Appraisal No 293 – Eltrombopag for treating chronic immune (idiopathic) thrombocytopenic purpura (review of technology appraisal 205)	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA293**	**Accepted for restricted use** **Indication under review:** For adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticoteroids, immunoglobulins). Eltrombopag may be considered as second-line treatment for adult non splenectomised patients where surgery is contraindicated. **SMC restriction**: in both splenectomised and non-splenectomised patient populations, restricted to use in patients with severe symptomatic IPT or a high risk of bleeding.	9/8/10	**No**
NICE (Single) Technology Appraisal No 294 – Aflibercept solution for injection for treating wet age-related macular degeneration	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA294**	**Accepted for use** In adults for the treatment of neovascular (wet) age-related macular degeneration	8/4/13	**No**

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE (Multiple) Technology Appraisal Guidance No 278 – Omalizumab for treating severe persistent allergic asthma	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA278**	**Accepted for restricted use** **Indication under review:** add-on therapy to improve asthma control in children (6 to <12 years of age) with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Omalizumab treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma. **SMC restriction:** use is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control.	5/3/10	**Yes**

HIS Comments on NICE Multiple Technology Appraisals	HIS Guidance Summary	SMC Decision and comments	Date of SMC decision	On Forth Valley formulary Yes/No
NICE (Multiple) Technology Appraisal Guidance No 279 – Percutaneous vertebroplasty and percutaneous balloon kyphoplasty (HIS advice to follow)	**Refer to NICE documentation for full guidance www.nice.org.uk/guidance/TA279**	**Would not go through SMC**	**N/A**	**No**

All information provided by this newsletter constitutes the most current advice of the Forth Valley Area Drug and Therapeutics Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in future.
For full SMC advice on specific drugs please refer to the SMC website **www.scottishmedicines.org**

Drugs Approved By SMC

Category 1	Included on the NHS Board formulary for the indication in question
Category 2	Included pending protocol
Category 3	Not included on the NHS Board Formulary because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary
Category 4	Not included on the NHS Board Formulary because clinicians do not support the formulary inclusion
Category 5	Not included on the NHS Board Formulary because clinicians have not responded to an invitation to apply for formulary inclusion to this medicine
Category 6	Not included pending protocol

The ADTC recommends that prescribers may prescribe these drugs in accordance with SMC advice.

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
Abatacept 125mg/mL solution for subcutaneous injection in a pre-filled syringe (Orencia®) **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.	**Category 1**
Adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) **Product Update**	**Accepted for restricted use** **Indication under review:** is indicated for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies. **SMC restriction:** prescribing by specialists in paediatric gastroenterology.	**Category 1**
Adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8ml solution for injection vial for paediatric use (Humira®) **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	children aged less than 2 years. **SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations.	
Argatroban, 100mg/ml, concentrate for solution for infusion (Exembol®) **Resubmission**	**Accepted for use** **Indication under review:** anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.	**Category 1**
Aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®)	**Accepted for restricted use** **Indication under review:** treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. **SMC restriction**: restricted to initiation and management under the supervision of a child/adolescent psychiatrist.	**Category 1**
Caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®)	**Accepted for use** **Indication under review:** treatment of primary apnoea of premature newborns.	**Category 1**
Calcium polystyrene sulphonate powder for oral/rectal suspension (Sorbisterit®) **Product Update**	**Accepted for use** **Indication under review:** treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment.	**Category 1**
Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumerate) 245mg film coated tablet (Stribild®)	**Accepted for use** **Indication under review:** treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment- naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®	**Category 1**
Etravirine 25mg, 100mg, 200mg tablets (Intelence®) **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age. **SMC restriction**: to be prescribed under the supervision of specialists in paediatric HIV.	**Category 1**
Latanoprost 50microgram/mL preservative-free single-dose eye-drops (Monoprost®)	**Accepted for restricted use** **Indication under review:** for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. **SMC restriction:** to use in patients who have proven sensitivity to the preservative benzalkonium chrloride.	**Category 1**
Linaclotide hard capsules, 290 micrograms (Constella®)	**Accepted for restricted use** **Indication under review:** Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults. **SMC restriction:** linaclotide is restricted for use in patients with	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options.	
Lixisenatide 10microgram/0.2mL, 20microgram/0.2ml solution for injection in pre-filled disposable pen (Lyxumia®)	**Accepted for restricted use** **Indication under review:** treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction**: to use in patients for whom a glucagon-like protein-1 (GLP-1) agonist is appropriate, as an alternative to existing GLP-1 agonists.	**Category 4**
Medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana®Press) **Product Update**	**Accepted for use** **Indication under review:** for long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year.	**Category 4**
Pegylated interferon alpha-2a, 135 and 180microgram/mL pre-filled pen (Pegasys®)	**Accepted for restricted use** **Indication under review:** in combination with ribavirin, is indicted for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA). When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case-by-case basis. **SMC restriction:** prescribing by specialist in paediatric infectious disease or paediatric gastroenterology.	**Category 1**
Pirfenidone 267mg capsule (Esbriet®) **Resubmission**	**Accepted for restricted use** **Indication under review:** in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). **SMC restriction:** for use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%.	**Category 1 – for specialist recommendation only**
Raltegravir 25mg, 100mg chewable and 400mg film-coated tablets (Isentress®) **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years. **SMC restriction**: to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir should to be prescribed under the supervision of specialists in paediatric HIV.	**Category 1**
Rifaximin 550mg film-coated tablets (Targaxan®)	**Accepted for use** **Indication under review:** reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥ 18 years of age.	**Category 1**
Rituximab 100mg, 500mg solution for infusion (MabThera®)	**Accepted for restricted use** **Indication under review:** in combination with glucocorticoids for the induction of remission in adult patients with severe, active	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). **SMC restriction**: to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide.	
Saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg tablets (Komboglyze®)	**Accepted for restricted use** **Indication under review:** adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets. **SMC restriction**: use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate.	**Category 4**
Tenofovir disoproxil (as fumerate) 123mg, 163mg, 204mg film-coated tablets (Viread®) **Product Update**	**Accepted for restricted use** **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. **SMC restriction**: to be prescribed under the supervision of specialists in paediatric infectious diseases.	**Category 1**
Tenofovir disoproxil (as fumerate) 245mg film-coated tablets (Viread®) **Product Update**	**Accepted for restricted use** **Indication under review:** *HIV-1 Infection* – in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. *Hepatitis B infection* – for the treatment of chronic hepatitis B in adolescents aged 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. **SMC restriction**: to be prescribed under the supervision of specialists in paediatric infectious diseases.	**Category 1**
Tenofovir disoproxil (as fumerate) 33mg/g oral granules (Viread®) **Product Update**	**Accepted for restricted use** **Indication under review:** *HIV-1 infection* – in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or to toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate. *Hepatitis B infection* – for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological	**Category 1**

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome
	evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. **SMC restriction**: in patients <18 years, to be prescribed under the supervision of specialists in paediatric infectious diseases.	
Ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) **Product Update**	**Accepted for use** **Indication under review:** for the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s). For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis.	**Category 1**

Process Flowchart (Appendix 1)

NHS FORTH VALLEY PRESCRIBING OF NEW MEDICINES FLOWCHART

This flowchart outlines the NHS Forth Valley process for the prescribing of new medicines. This follows guidance from the Scottish Government for the managed introduction and availability of newly licensed medicines in NHS Scotland